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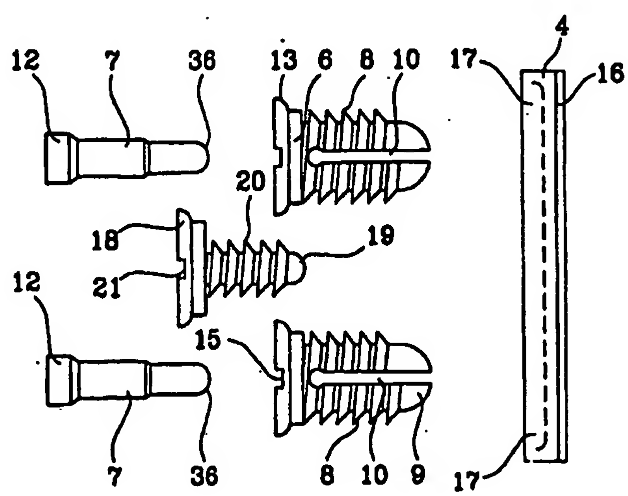

(57) Abstract

A vertebral fusion system including a rigid plate (4, 52) defining first and second orifices (16, 94, 96) alignable with first and second vertebrae (5), and further including at least two anchor assemblies (2, 54). Each assembly includes an outer anchor member (6, 56) and an inner cam member (7, 58), the outer anchor member (6, 56) being insertable in a contracted condition through one of the first and second orifices (16, 94, 96) and into one of the first and second holes in the vertebrae (5). The outer member (6, 56) defines an internal bore (30, 116) for receiving the inner cam member (7, 58) therein, and includes a plurality of outwardly expandable legs. Portions of the internal bore (30, 116) and of the inner cam member (7, 58) define matching detent and recess regions (8, 120) to enable the inner cam member (7, 58) to be successively interlocked at positions of increasing depth within the outer anchor member (6, 56) as the inner member (7, 58) is driven into the outer member (6, 56). As the inner cam member (7, 58) is driven into the outer anchor member (6, 56), the legs are driven outwardly into an expanded condition to secure the plate (4, 52) and the anchor assemblies (2, 54) together and thereby immobilize the first and second vertebrae (5). Preferably, the system includes a washer (60) which positively locks each anchor assembly (54) with the plate (52).

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VERTEBRAL FUSION SYSTEM WITH EXPANDABLE ANCHOR

FIELD OF INVENTION

This invention relates to a system of treating spine pathologies following implantation of a graft in the intervertebral space formed by disc removal, and more particularly to a system having a plate and expandable anchor members to immobilize the vertebrae and graft to attain good bone consolidation.

TECHNICAL FIELD

As is known, spine surgery is indicated in multiple processes, including traumatic, degenerative, inflammatory, tumoral and congenital pathologies. The upper region of the spine is known as the cervical region, which is further defined as the high cervical spine, which includes the first and second cervical vertebrae, and the lower cervical spine, which includes the 3rd-7th vertebral segments. Injuries at these levels are much more frequent and require specific surgical treatment more often.

In this regard, cervical spine pathologies can be approached from two directions: the posterior approach which requires performing a laminectomy and the anterior approach which involves access through the anterior or anterolateral aspect of the neck. The latter is more widely used since the pathology has a more frequently anterior location in the vertebrae themselves or the intervertebral discs.

A vertical or transverse incision, located on the anterior edge of the sternocleidomastoid muscle, is made to access the prevertebral space between the vascularcarotid-jugular bundle on the outside and the pharynx-larynx on the inside. The anterior common longitudinal ligament is removed, exposing the discs and vertebrae at one or more levels. The next step depends on the type of pathology to be treated (somatic or discal vertebral), but in any case, a general repercussion is a uni- or multi-segment instability caused by the pathology itself, the ligament interruption or the removal of the disc or portions of the vertebrae. Cervical spine instability therefore is the most frequent side-effect of a surgical procedure using the anterior approach..

In 1958 Cloward proposed the placement of an intersomatic graft in the intervertebral space produced upon disc removal. After removing the disc with a specially designed drill, a cylindrical cavity extending to the body of the superior and inferior vertebrae is created in the intervertebral space, following which another drill of similar diameter is used to obtain a cylinder of spongy bone tissue from the ala of the ilium. This cylinder is introduced into the cavity created in the intervertebral space in order to attain bone fusion. Recently Otero modified the technique in such a way that the bone cylinder and the intervertebral cavity are threaded so as to facilitate graft placement.

Cloward's technique has been and is still being widely utilized. It achieves good bone consolidation in the space of two or three months. Its disadvantages are the obtaining of the graft and

the risk of perforating the posterior vertebral wall, thus producing a medullar injury.

In 1958, Smith and Robinson published their technique, which is similar to that of Cloward. The intervertebral space produced upon disc removal is filled with a bone graft taken from the iliac crest. The procedure is technically simpler than Cloward's but has the disadvantage that the placement of the graft in its new location is weaker. Extension movements of the cervical spine can cause the bone to be expelled forward.

Verbiest, to avoid this latter problem, proposes carving the vertebral platforms after removing the disc in such a way that they form a wedge-shaped cavity with an anterior base. The graft is also cut in the shape of a wedge. By producing a forced extension of the cervical spine, it is possible to position the graft in its cavity, but this requires very meticulous and long surgery.

In order to avoid the problems of graft expulsion by ensuring cervical spine immobility during the consolidation process, in 1972, Orozco and Llobet began to use small screwed plates anchored in the adjacent vertebral bodies. There are many models and types of plates and screws. Practically all of them have the same disadvantages. The high degree of mobility of the cervical spine causes the osteosynthesis material to be expelled. To avoid this, the anchoring screws must cross the posterior cortical layer of the vertebral body, with the added risk of medullar lesion.

A most recent technique reported by Caspar utilizes large plates, about 15 or 20cm wide, which cover the anterior face of the vertebral bodies and of the removed disc. The plates are anchored to the vertebrae by several screws, two for each level. The solidity obtained is greater but the surgery required is more aggressive and longer and there is still a risk of medullar injury produced by the screws, which must perforate the posterior cortical layer of the vertebra.

Synthes presently markets screws which expand at the head level when another small central screw is introduced into them to engage the plate. This provides greater solidity of the screw-plate bond with a reduction in mobility.

Codman and Shirtleff sells a screw and plate system having a small, oval-headed locking screw which is installed in the plate next to the scalloped head of the main anchoring screw to interlock the main screw to the plate. If the locking screw rotates, however, the plate may shift thereafter.

One or more of the following problems are found in the above-described techniques:

- Risk of medullar injury produced by the need to perforate the posterior wall of the vertebral body to anchor the screws;
- Meticulousness of the technique, due to the previously mentioned risk, which requires the prolonged usage of a radiological imaging intensifier and its inherent risks for the surgeon;

- Frequency with which mobilization of the osteosynthesis material occurs with the risk of expulsion and requirement for additional surgery due to the high degree of mobility of the cervical spine;
- Necessity of prolonged immobilization through use of a post-operative collar to avoid complications arising from the expulsion of the material; and
- Length and aggressiveness of the surgery, with the need to expose many fields, to separate the muscles from the anterior spine.

DISCLOSURE OF INVENTION

A vertebral fusion system and method according to the present inventor ensures a solid anchoring of a plate to the vertebrae. The preferred embodiment includes a plate installed on the anterior face of the vertebrae, expandable anchor screws which pass through the plate and are then attached to the vertebrae itself, and a screw or screws which also pass through the plate and are attached to a graft implanted between the vertebrae. The anchoring screws for the vertebrae are cylindrical, preferably 12mm long and 7-8mm in diameter, have a wide thread and a blunt point, and are self-tapping. These screws are called anchoring screws because another small screw is placed within their center. For this purpose, the anchoring screw features longitudinal slits about 4-5mm long and is hollow and threaded on the inside so as to hold the inner screw. This inner screw opens the anchoring screw's legs as it enters and increases

its diameter when the inner screw is in place. This increase typically is 25-30% with respect to the original diameter and provides a solid anchoring to the vertebra.

The screw or screws which pass through the plate and anchor the graft are conventional screws with a head which stays positioned in the previously mentioned recess in the corresponding plate. These screws consist solely of a simple shank with an appropriate thread and its respective head.

Both the vertebrae anchoring screws and the graft anchoring screws, as well as the plates themselves, are made preferably of titanium to ensure the possibility of post-operative exploration through magnetic resonance imaging. The anchoring screw's external surface, including its spiral or thread, is coated with hydroxyapatite to facilitate the implant's solidity and encourage bone growth around it.

In another embodiment the system includes a locking washer having two or more legs which straddle recesses in the head of an anchoring screw and interlock with recesses in the plate to positively ensure immobilization.

Based on these structural and application characteristics, the advantages offered by this system of plates and expandable anchors can be summarized as follows:

- Solidity of the system which hinders the expulsion of the osteosynthesis, through the distal dilation of the

anchoring screw;

- The risks of performing the posterior cortical layer of the vertebral body are avoided since this perforation is no longer necessary;
- The irradiation time for the surgeon is reduced since radiological monitoring is practically unnecessary since the anchoring screws are quite short and can never perforate the posterior wall;
- The severity of the surgery itself is reduced since the material to be implanted does not require large incisions or prevertebral muscular detachment;
- The need for a collar or any other form of post-operative immobilization becomes unnecessary, due to the asssembly's solidity; and
- Fusion is ensured even in patients with osteoporotic bones.

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects, features and advantages will occur from the following description of preferred embodiments and the accompanying drawings, in which:

Fig. 1 is a schematic vertical lateral view of cervical vertebrae with the system implemented according to the present invention;

Fig. 2 is a schematic front (anterior) view of the same applied system;

Fig. 3 is a lateral exploded view of the different elements making up the present invention;

Fig. 4 is a longitudinal cross-sectional view of the expandable anchor screw according to the present invention;

Fig. 5 is a bottom-end view of the distal point of the anchoring screw of Fig. 4 in which the slits in form of a cross can be seen;

Fig. 6 is a top view of one construction of the plate used according to the present invention;

Fig. 7 is a cross-sectional view of the plate shown in Fig. 6;

Fig. 8 is a side view of another construction of the expandable screw;

Fig. 9 is a cross-sectional view of another construction of a plate with two expandable screws, of the type shown in Fig. 8, inserted at divergent angles;

Fig. 10 shows another construction of the plate with two orifices and a central orifice with a smaller radius;

Fig. 11 is a cross-sectional view of the plate of Fig. 10 along the line A-A;

Fig. 12 is a longitudinal profile of the non-bendable plate curved to match the anterior profile of the cervical spine;

Fig. 13 is a schematic perspective view of a locking washer according to the present invention;

Fig. 14 is a schematic view of a presently preferred anchor member according to the present invention having recesses for receiving the locking washer of Fig. 13;

Fig. 15 is a schematic perspective view of a plate according to the present invention having channels for receiving the legs of the locking washer of Fig. 13; and

Fig. 16 is a schematic perspective view of the locking washer, anchor, and plate of Figs. 13-15 assembled together with an inner screw for securing the assembly together.

MODE FOR CARRYING OUT THE INVENTION

The present system and method are particularly useful for treating cervical spine pathologies through the anterior approach and are specifically applicable to intervertebral disc surgeries, so that once the disc is removed, the resulting intervertebral cavity contains a graft, Figs. 1 and 2. This graft 1 is immobilized precisely by the invention's system which consists of two anchoring screw assemblies 2, a graft screw 3, and a plate 4 in such a way that the screw assemblies 2 are anchored to the corresponding vertebrae 5 while the screw 3 is anchored to the graft 1. This secures the plate to the anterior face of the vertebrae 5 precisely by means of these screws.

As shown in Figs. 3-5, each screw assembly 2 includes an anchoring screw 6 and an inner cam screw 7, both preferably made of the same material, particularly titanium. The anchoring screw 6 is hollow and contains an outer spiral 8 consisting of a thread, a distal blunt point 9 and longitudinal slits 10 in the form of a cross to establish four outwardly expandable legs. The inside of this anchoring screw 6 defines an internal bore 30 having a thread or spiral 11 to match the thread of the inner screw 7. This inner screw has a head 12 with a drive socket permitting the use of an Allen wrench, screwdriver or other appropriate tool. The anchoring screw 6 also has the unique feature that its head 13 has a cavity 14 designed to hold the head 12 of screw 7 and also has several slots 15 to allow it to be handled by an appropriate tool or similar instrument.

The anchoring screws 6 defines inner camming surfaces 32, 34, Fig. 4, distal to the internal threads 11, which are slideably engaged by camming surfaces 36, Fig 3, of the inner screws 7. The anchoring screws 6 are thereby driven from the contracted position shown in Fig. 3 to the expanded position schematically shown in Fig. 1.

The plate 4, Figs. 6-7, preferably is also made of titanium and has a flat-rectangular configuration, with orifices 16 to permit the passage of screws 2 and 3 which are indented around their perimeter 17 to accommodate the respective heads 13 of screws 2 and for the heads 18 of the screws 3 utilized for the graft. These latter screws consist of a simple shank with a distal rounded point 19, a thread or external spiral 20 and head 18, also with the

necessary slots 21 to permit handling with an appropriate tool. These screws 3 preferably are made of titanium just as are the elements previously mentioned.

During use, first and second holes are drilled in first and second vertebrae 5, Fig. 1. The anchoring screws 6 are introduced in the contracted condition into the corresponding vertebrae 5, after passing through the orifice 16 of the plate 4, then the inner cam screw 7 is inserted into each anchoring screw 6. As this inner screw 7 is advanced, it causes the legs and therefore the distal region of the anchoring screw 6 to expand into the expanded condition as is presented schematically in Fig. 1. This provides a secure anchoring of these screws 2 to the vertebrae 5 and thus, immobilizing the plate 4, and hindering the mobility and expulsion of the graft 1. Screw 3, placed into a smaller-diameter pre-drilled hole in the graft 3, aids in the immobilization of the graft.

The anchoring screws 6 shown in Figs. 8 and 9, have the advantage that their heads 18 are curved at edges 22 to permit the angle of insertion into the hole 16 of the plate 4 to be varied and not necessarily be perpendicular. Thus, each screw can be inserted in a different direction relative to the plate, reinforcing the stability of the axial and lateral rotation of the vertebrae.

Plate 4, which has been shown in one of its possible applications with three orifices 16 can contain more orifices and even be wider or narrower. Thus, as shown in Figs. 10, 11 and 12, the plates for

two vertebral levels will have two large orifices 16 and a central orifice 24 of smaller radius. As a result, the plate 4 is more solid and weak points are eliminated. The two-level plates can be constructed in various sizes and with lengths of 23, 27, 31 and 34 millimeters to accommodate the size of each patient's vertebrae.

The plates 4 in one construction have a three-millimeter prong 23 emerging perpendicularly from its posterior face - the one applied to the vertebra - and at the same horizontal level as the orifices 16 for the expandable screw. These prongs are located on each side and are embedded into the vertebra's anterior face, thus preventing shifts during lateral flexion and axial rotation.

More generally, a vertebral fusion system according to the present invention includes a rigid plate defining first and second orifices spaced from each other, and at least two anchor assemblies, each assembly including an outer anchor member and an inner cam member, each of the inner and outer members having a distal region and a proximal region. Each outer anchor member is insertable in a contracted condition through one of the first and second orifices and into one of the first and second holes. Each outer anchor member defines an internal bore for receiving the inner cam member therein, and portions of the internal bore and of the inner cam member define matching detent and recess regions, such as matching threads, to enable the inner cam member to be successively interlocked at positions of increasing depth within the outer anchor member as the inner member is driven into the outer member. The matching detent and recess

regions alternatively are a series of ribs and grooves into which the ribs successively snap when at least one of the inner and outer members are formed of a sufficiently resilient material. The outer anchor member defines a plurality of outwardly expandable legs, each leg having outer ridges on its outer surface, the ridges being barbs, ribs, or a helical thread.

Vertebral fusion system 50, Figs. 13-16, is a preferred construction in which a plate 52 is secured in position with an anchor assembly 54 including an outer anchor member 56 and an inner cam member 58. Fusion system 50 further includes a locking washer 60 having at least first and second legs 62, 64, Fig. 13, connected by a ring 66 defining a central passage 68 through which inner camming member 58 is insertable as shown in Fig. 16. Each leg 62, 64 includes first, horizontal portions 70, 72 and second, vertical portions 74, 76, respectively. The first portions 70, 72 rests within recesses 80, 82 of anchor member 56, and the second portions 74, 76 slideably engage washer leg slots 90, 92 of plate 52, Fig. 15.

Plate 52 further defines first orifice 94, second orifice 96, and a smaller-diameter third orifice 98 located between the first and second orifices 94, 96. A graft screw (not shown) is insertable through the third orifice 98 to engage a graft placed between first and second vertebrae positioned under orifices 94, 96, respectively. Preferably, the vertebral side of the plate 52 is textured with a diamond-type knurl finish to enhance bone-to-plate interlocking and resist shifting.

Recesses 80, 82, of outer anchor member 56 are defined by posts 100, 102, 104 and 106 which abut against the sides of first portions 70, 72 of the washer 60. In another construction, the washer 60 includes four legs which rest between all four posts 100, 102, 104 and 106, and plate 52 defines at least four washer leg slots communicating with each outer orifice 94, 96.

Outer anchor member 56 defines four legs, three of which are shown as legs 110, 112, and 114. When inner cam member 58 is inserted into internal bore 116 of outer anchor member 56, smooth outer camming surface 118, Fig. 16, engages smooth inner camming surfaces on the legs 110, 112, 114 and 116 to drive the legs outwardly from the contracted condition shown in Figs. 14 and 16 into an expanded condition in which the walls of holes drilled in the vertebrae are securely engaged by the interrupted helical thread 120. Matching detent and recess regions are provided in outer anchor member 56 and as region 122 of inner cam member 58. In one construction, the matching detent and recess regions include number ten machine threads. A hexagonal socket 124 mates with a driver to enable the inner cam member 58 to be rotatably driven into the outer anchor member 56.

In another arrangement, each outer anchor member defines an enlarged proximal head having a collar or annulus and a smaller-diameter polygonal projection, such as a hexagonal plateau, which extends proximally beyond the collar. The plate defines orifices shaped in matching polygons. During use, the outer anchor members are installed in bone first, and then the plate is positioned on top of the anchor

members to rest on the collars and interlock the polygonal projections with the polygonal orifices.

Inner cam members are provided with enlarged proximal heads to lock the plate to the outer anchor members. The heads of the cam members define one or more channels engagable by a slotted screw driver. Preferably, the edges of the orifices at the upper, distal side of the plate define recesses into which the heads of the cam members are positionable to reduce the profile of the fusion system.

In one construction, the outer anchor member has an overall length of 14.8mm, a root diameter of 5.5mm, an outer thread diameter of 7.5mm, and four leg-defining slots of 10.7mm length. Inner camming surfaces are defined at thirty degree angles relative to the longitudinal axis of the outer anchor member.

Although specific features of the invention are shown in some drawings and not in others, this is for convenience only as each feature may be combined with any or all of the other features in accordance with the invention.

Other embodiments will occur to those skilled in the art and are within the following claims.

CLAIMS

1. A vertebral fusion system for immobilizing first and second vertebrae having at least first and second holes drilled in the respective vertebrae, the system comprising:

a rigid plate (4,52) defining at least first and second orifices (16) spaced from each other and alignable with the first and second vertebrae (5) respectively;

at least two anchor assemblies (2,54), each assembly including an outer anchor member (6) and an inner cam member (7,58), each of said inner and outer members (6,7,56,58) having a distal region and a proximal region;

each said outer anchor member (6,56) being insertable in a contracted condition into one of the first and second holes and defining an internal bore (30,116) for receiving said respective inner cam member (7,58) therein;

portions of said internal bore (30,116) and of said respective inner cam member (7,58) defining matching detent and recess regions (11) to enable said inner cam member to be successively interlocked at positions of increasing depth within said outer anchor member as said inner member is driven into said outer member;

each said outer anchor member (6,56) defining a plurality of slits (10) in its distal region communicating with said internal bore (30) to establish a plurality of outwardly expandable legs, each said leg defining outer ridges (8,120) on its outer surface for engaging a wall of one of the holes drilled in the vertebrae, and defining an inner camming surface (32,34) distal to one of said detent and recess regions (11); and

each said inner cam member (7,58) defining an outer camming surface (36,118) for slidably engaging said inner camming surface (32,34) of said outwardly expandable legs, as said inner cam member (7,58) is driven into its respective outer anchor member (6,56) to drive said legs outwardly into an expanded condition to engage the wall of the drilled hole to immobilize the first and second vertebrae (5).

2. The fusion system of claim 1 wherein said outer ridges (8,120) defined on said legs of each said outer anchor member are portions of a helical thread, said thread being interrupted by said plurality of slits (10).

3. The fusion system of claim 1 wherein said matching detent and recess regions (11) of each said internal bore and each said inner cam member are matching helical threads to enable said inner member to be screwed into said outer member.

4. The fusion system of claim 1 wherein each said outer member (6) defines four slits (10) and four outwardly expandable legs.

5. The fusion system of claim 1 further including a washer (60) which is interlockable with said plate and one of said anchor assemblies.

6. The fusion system of claim 5 wherein said plate includes at least two slots (90,92) communicating with one of said first and second orifices (94,96), and said washer (60) includes at least two legs (74,76) which engage said slots (94,96).

7. The fusion system of claim 6 in which each said outer anchor member (56) defines recesses (80,82) in its proximal region for receiving a portion of said legs (72,74) of said washer (60).

8. The fusion system of claim 7 wherein said washer (60) defines a passage (68) through which one of said inner cam members (7) is insertable to lockably engage said washer (60) to said anchor assembly (50) and said plate (52).

9. A vertebral fusion system for immobilizing first and second vertebrae having at least first and second holes drilled in the respective vertebrae, the system comprising:

a rigid plate (4,52) defining first and second orifices (16,94,96) spaced from each other and alignable with the first and second vertebrae (5), respectively;

at least two anchor assemblies (2,54), each assembly including an outer anchor screw (6,56) and an inner cam screw (7), each of said inner and outer screw having a distal region and a proximal region;

each said outer anchor screw (5,56) being insertable in a contracted condition through one of said first and second orifices (16,94,96) and into one of the first and second holes, and defining an internal bore (30,116) for receiving said inner cam screw (7) therein;

portions of said internal bore (30,116) and of said inner cam screw (7) defining matching threads (11) to enable said inner cam screw to be successively interlocked at positions of increasing depth within said outer anchor screw (6,56) as said inner screw (7) is rotatably driven into said outer screw (6,56);

each said outer anchor screw (6,56) defining a plurality of slits (10) in its distal region communicating with said internal bore (30,116) to establish a plurality of outwardly expandable legs, each said leg defining outer ridges (8,120) on its outer surface for engaging a wall of one of the holes drilled in the vertebrae, and defining an inner camming surface distal to one of said detent and recess regions; and

each said inner cam screw (7,58) defining an outer camming surface (36,118) for slidably engaging said inner camming surface of said outwardly expandable legs, as said inner cam screw (7,58) is driven into its respective outer anchor screw (6,56) to drive said legs outwardly into an expanded condition to engage the wall of the drilled hole to secure said plate (4,52) and said anchor assemblies (2,54) together and thereby immobilize the first and second vertebrae (5).

10. The fusion system of claim 9 wherein said outer ridges (8,120) defined on said legs of each said outer

anchor screw are portions of a helical thread interrupted by said plurality of slits (10).

11. The fusion system of claim 10 wherein each said outer screw (6,56) defines four slits (10) and four outwardly expandable legs.

12. The fusion system of claim 11 wherein said rigid plate (4,52) further defines a third orifice (24,98) between said first and second orifices (16,94,96), said third orifice (24,98) being alignable with a graft placed between said first and second vertebrae.

13. The fusion system of claim 12 further including a graft screw (3) insertable through said third orifice (24,98) to engage the graft.

14. A method for immobilizing first and second vertebrae (5) comprising:

drilling first and second holes in the first and second vertebrae (5);

providing a rigid plate (4,52) defining at least first and second orifices (16,94,96) spaced from each other, and installing the plate (4,52) to align the first and second orifices (16,94,96) with the first and second holes;

providing at least two anchor assemblies (2,54), each assembly including an outer anchor member (6,56) and inner cam member (7,58);

inserting said outer anchor members (6,56) through the first and second orifices (16,94,96) into the first and second holes; and

driving the inner cam members (7,58) into the outer anchor members (6,56) to expand legs of the outer anchor members into an expanded condition to engage the walls of the drilled holes to secure the plate (4,52) and the anchor assemblies (2,54) together and thereby immobilize the first and second vertebrae (5).

15. The method of claim 14 further including installing a washer (60) between each inner cam member (58) and each outer anchor member (56) to positively lock each anchor assembly (54) with the plate (52).

16. The method of claim 15 wherein said plate (52) includes at least two slots (90,92) communicating with one of said first and second orifices (94,96), and said washer (60) includes at least two legs (72,74) which engage said slots (90,92).

17. The method system of claim 16 in which each said outer anchor member (56) defines recesses (80,82) in its proximal region for receiving a portion of said legs (72,74) of said washer (60).

18. The method system of claim 17 wherein said washer (60) defines a passage (68) through which one of said inner cam members (58) is insertable to lockably engage said washer (60) to said anchor assembly (54) and said plate (52).

19. The method of claim 18 in which the plate (52) defines a third orifice (98) between the first and second orifices, and further including installing a graft between the first and second vertebrae, and driving a screw through the third orifice (98) and into the graft.

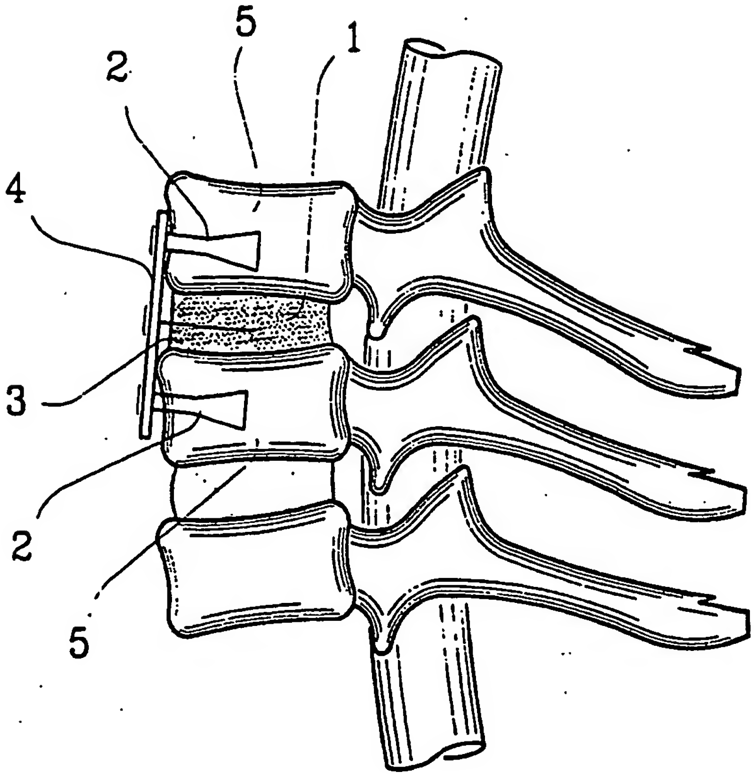


FIGURE 1

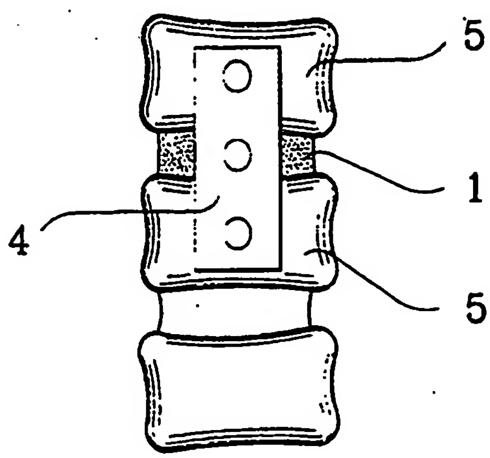


FIGURE 2

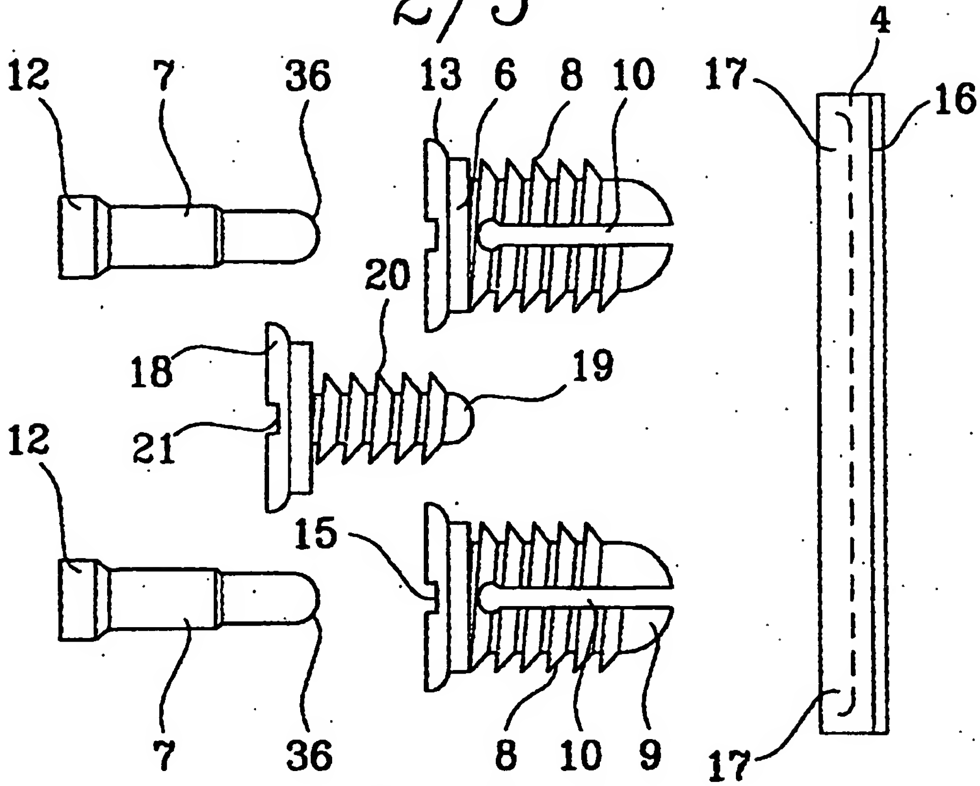


FIGURE 3

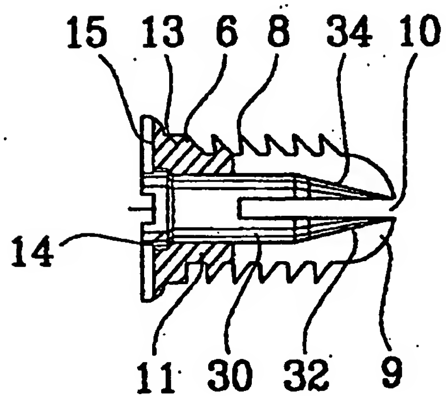


FIGURE 4

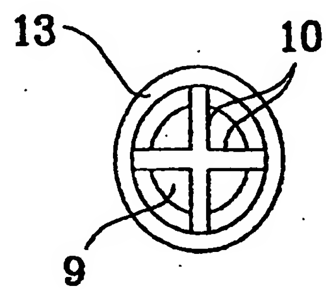
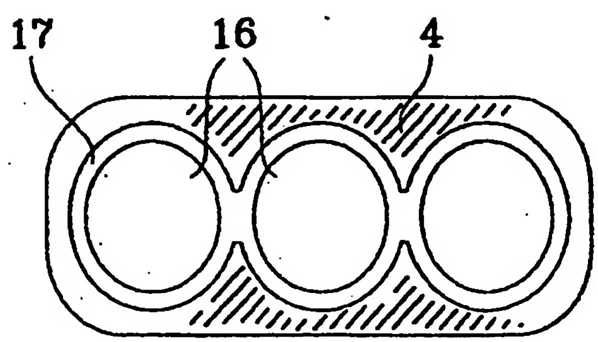


FIGURE 5



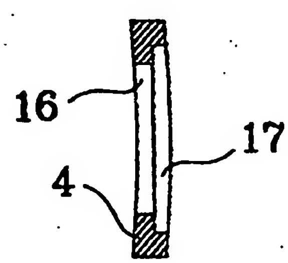


FIGURE 6

FIGURE 7

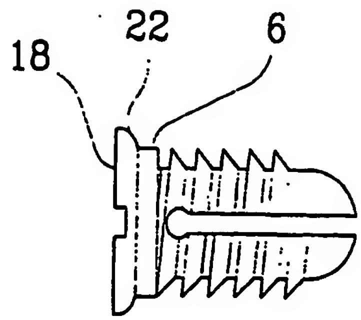


FIGURE 8

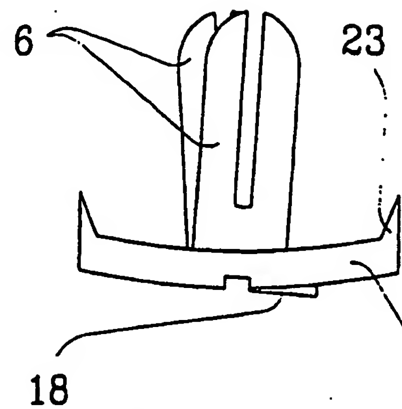


FIGURE 9

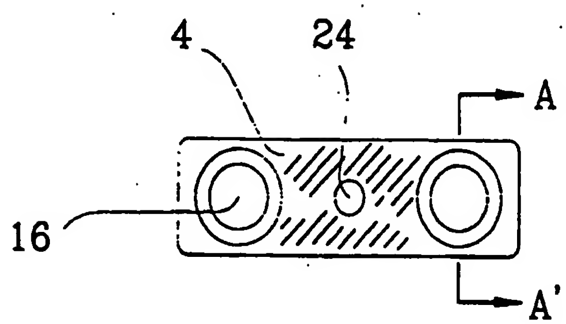


FIGURE 10

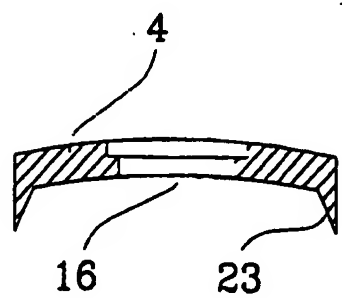


FIGURE 11

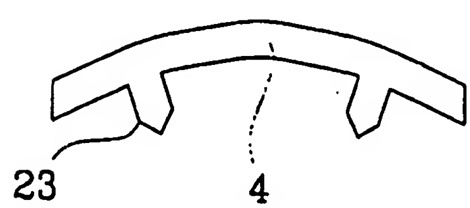


FIGURE 12

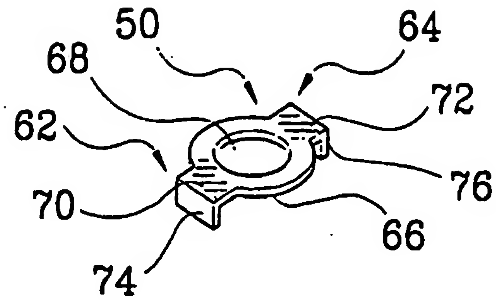


FIGURE 13

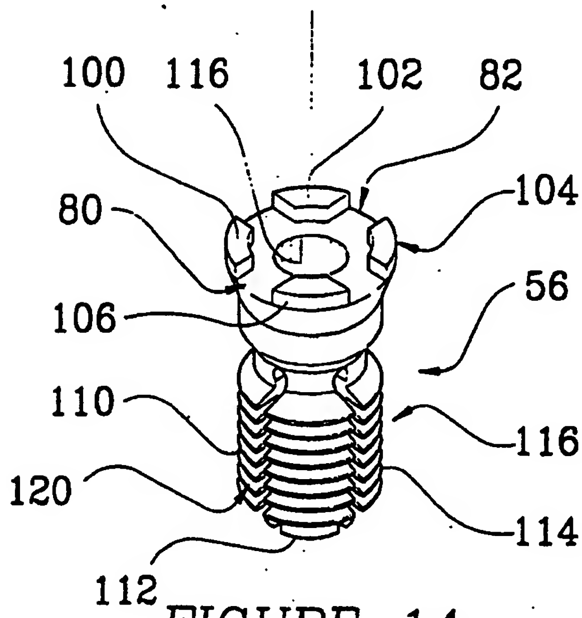


FIGURE 14

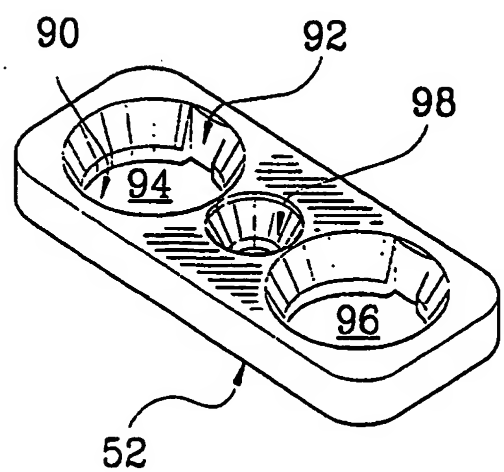


FIGURE 15

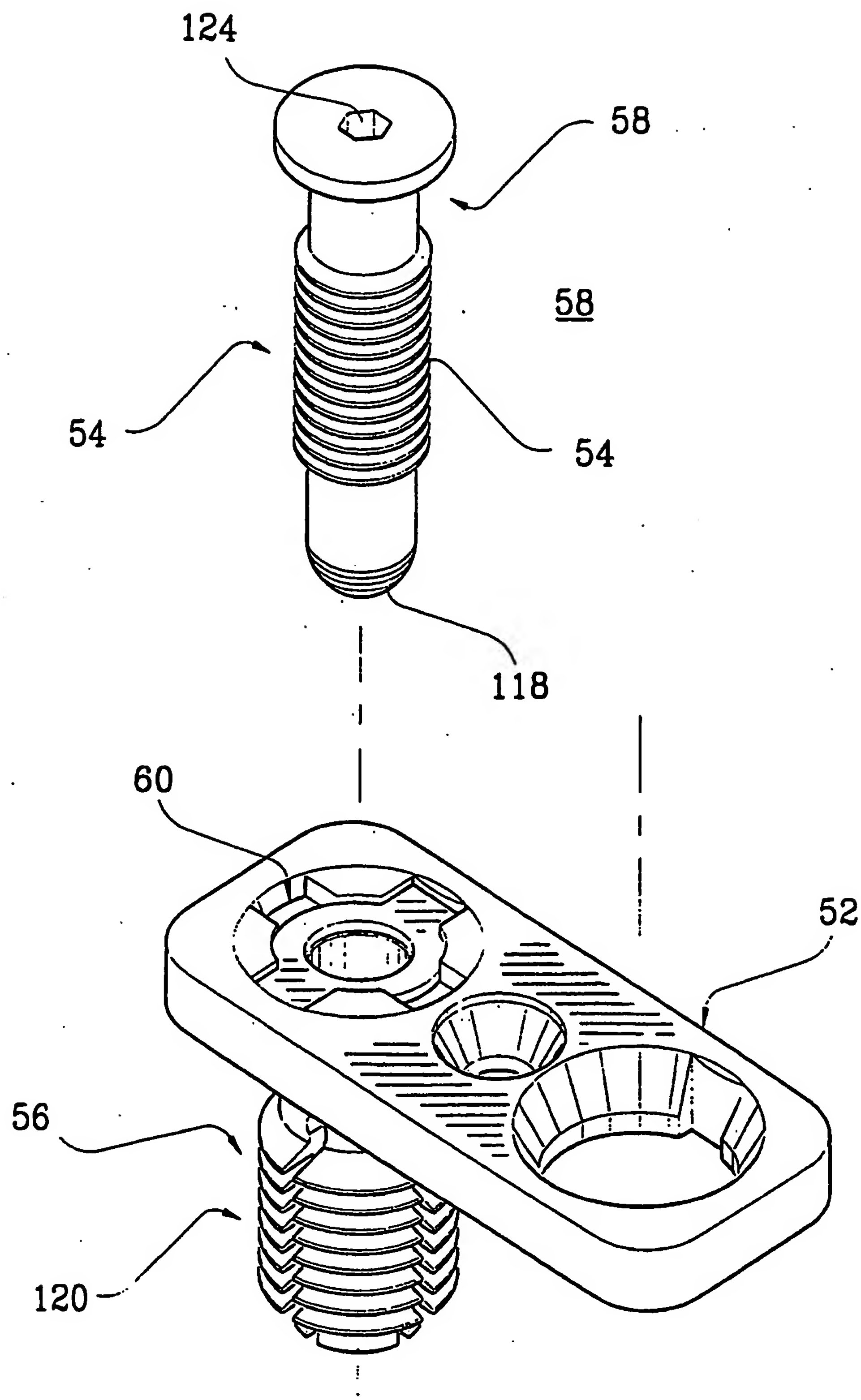


FIGURE 16

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/70, 17/80, 17/86; F16B 13/06, 39/02
US CL :411/60, 271; 606/61, 69, 73
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 411/55, 60, 109, 119, 120, 271; 606/61, 69, 70, 71, 73

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 5,041,113, (BIEDERMAN ET AL.), 20 August 1991. See Figs. 1-8.	1-6, 9-16
Y	US, A, 5,209,753, (BIEDERMAN ET AL.), 11 May 1993. See Figs. 1 and 2.	1-6, 9-16
A	US, A, 1,816,970, (G. HESS), 04 August 1931. See Figs. 1-2.	1-19
A	US, A, 2,822,014, (L. A. CUMMARO), 04 February 1958. See Figs. 1-3.	1-19
A, P	US, A, 5,344,421, (CROOK), 06 September 1994. See Figs. 1-4.	1-19

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
02 AUGUST 1995	24 AUG 1995

Name and mailing address of the ISA/US	Authorized officer
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